

**Notice of Allowability**

Application No.

10/049,192

Applicant(s)

COLAU ET AL.

Examiner

Art Unit

Louise Humphrey, Ph.D.

1648

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on 19 April 2007.
2. ☒ The allowed claim(s) is/are 94-115, 120 and 146.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

  
JEFFREY S. PARKIN, PH.D.  
PRIMARY EXAMINER

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicants' representative, Elizabeth Hecht, on 7 May 2007.

Please cancel claims 40-56, 77 and 78.

Claims 94-115, 120 and 146 are pending and allowable.

The following is an examiner's statement of reasons for allowance:

The rejection of claim 92 under 35 U.S.C. §112, 2<sup>nd</sup> ¶, as being indefinite is withdrawn in response to Applicants' cancellation of the claim.

The rejection of claim 92 under 35 U.S.C. §112, 1<sup>st</sup> ¶, as containing subject matter that was not described in the specification in a way that is commensurate in scope of the invention is withdrawn in response to Applicants' cancellation of the claim.

The rejection of claim 92 under 35 U.S.C. §102, as being anticipated by, or in the alternative, under 35 U.S.C. §103(a), as being obvious over Hoshino *et al.* (US 2002/0058043) is withdrawn in response to Applicants' cancellation of the claim.

The instant invention meets both the enablement and prior art requirements based on the following:

The claimed invention is fully enabled because it has been demonstrated to have positive outcome in clinical trials under the strain name RIX4414, or Rotarix (Vesikari, 2004, pp. 2837, 2.1. *Vaccine*). The name of vaccine comprising strain RIX4414 is Rotarix, which has been demonstrated to be safe and efficacious (Ruiz-Palacios, 2006) and licensed and used in Europe (Glass, 2006).

The closest prior art is Bernstein *et al.* (1998, No. CC in IDS), who teach the safety and immunogenicity of the heterogenous and live attenuated human rotavirus preparation, P33, which is produced by 33 serial passages of the rotavirus strain 89-12. The instant invention is directed to the homogenous rotavirus, P43, that is produced by subjecting P33 to 10 more serial passages in cell culture and thereby purifying the P33 variant to a single strain. Bernstein *et al.* does not teach or fairly suggest further serial passages of P33 or the claimed P43 rotavirus of a genotype with the six mutations in the VP4 and VP7 gene regions. One skilled in the art cannot predict the genotypic characteristic of the instant invention from the prior art of record because Bernstein *et al.* do not teach any genotypic characterization of P33 and since each serial passage of the P33 virus has a change of genetic mutation during virus replication.

Accordingly, claims 94-115, 120 and 146 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Correspondence***

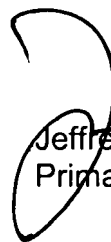
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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07 May 2007



Jeffrey Parkin, Ph.D.  
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